



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO		<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/825,908-Conf. # 8944
		Filing Date	April 16, 2004
		First Named Inventor	James M. Harris
		Art Unit	1637
		Examiner Name	Suchira Pande
		Attorney Docket Number	020187.0100/P-5677
Sheet	1	of	3

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)				
↓  <						

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)					
SP	BA	EP-0 317 077		1-31-96	Urdea et al.		
↓	BB	EP-0 353 985		2-7-90	Woods et al.		
	BC	EP-0 497 272		8-5-92	Walker		
	BD	EP-0 624 643		11-17-94	Fraiser et al.		
	BE	EP-0 678 582		10-25-95	Nadeau et al.		
	SP	BF	EP-0 684 315		11-29-95	Fraiser et al.	

Examiner Signature	/Suchira Pande/	Date Considered	02/04/2007
-----------------------	-----------------	--------------------	------------

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete If Known</b>	
				Application Number	10/825,908-Conf. # 8944
				Filing Date	April 16, 2004
				First Named Inventor	James M. Harris
				Art Unit	1637
				Examiner Name	Suchira Pande
Sheet	2	of	3	Attorney Docket Number	020187.0100/P-5677

SP	BG	EP-0 747 489	12-11-96	Yang et al.		
	BH	EP-0 823 485	2-11-98	Wyrich et al.		
	BI	WO-89/03891	5-5-89	Urdea et al.		
	BJ	WO-90/10064	9-7-90	Miller		
	BK	WO-91/03573	8-25-90	Kessler et al.		
SP	BL	WO-94/06817	3-31-94	Chmelo		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SP	CA	BARANY, <u>Genetic Disease Detection and DNA Amplification Using Cloned Thermostable Ligase</u> , <i>Proc. Natl. Acad. Sci. USA</i> , <b>88</b> (1): 189-93 (1991)	
	CB	BARRINGER et al., <i>Gene</i> , <b>89</b> :117-122 (1990)	
	CC	BUIMER et al., <u>Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> by Ligase Chain Reaction-Based Assays with Clinical Specimens from Various Sites: Implications for Diagnostic Testing and Screening</u> , <i>J. Clinical Microbiology</i> , <b>34</b> (10):2395-2400 (Oct. 1996)	
	CD	CHAN et al., <u>Performance Characteristics of the Becton Dickinson ProbeTec System for Direct Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in male and female urine specimens in comparison with the Roche Cobas System</u> , <i>Arch. Pathol. Lab. Med.</i> , <b>124</b> (11): 1649-52 (2000)	
	CE	CROTCHFELT et al., <u>Detection of <i>Neisseria gonorrhoeae</i> and <i>Chlamydia trachomatis</i> in Genitourinary Specimens from Men and Women by a Coamplification PCR Assay</u> , <i>J. of Clinical Microbiology</i> , <b>35</b> (6):1536-1540 (June 1997)	
	CF	DONEGAN, JAMES J. <u>Isolation of a species-specific DNA probe for <i>Neisseria gonorrhoeae</i> using a novel technique particularly suitable for use with closely related species displaying high levels of DNA homology</u> , <i>Mol. Cell. Prob.</i> , <b>3</b> : 13-26 (1989)	
	CG	GUATELLI et al., <u>Isothermal, in vitro Amplification of Nucleic Acids by a Multienzyme Reaction Modeled After Retroviral Replication</u> , <i>Proc. Natl. Acad. Sci. USA</i> , <b>87</b> (5): 1874-8 (1990)	
	CH	HERRMANN et al., <u>Detection of <i>Neisseria gonorrhoeae</i> from Air-Dried Genital Samples by Single-Tube Nested PCR</u> , <i>J. of Clinical Microbiology</i> , <b>34</b> (10):2548-2551 (Oct. 1996)	
	CI	IWEN et al., <u>Evaluation of Nucleic Acid-Based Test (PACE 2C) for Simultaneous Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> in Endocervical Specimens</u> , <i>J. of Clinical Microbiology</i> , <b>33</b> (10):2587-2591 (Oct. 1995)	
	CJ	JEPHCOTT, A.E., <u>Microbiological Diagnosis of Gonorrhoea</u> , <i>Genitourin Med.</i> , <b>73</b> :245-252 (1997)	
	CK	KWOH et al., <u>Transcription-based Amplification System and Detection of Amplified Human Immunodeficiency Virus Type 1 with a bead-Based Sandwich Hybridization Format</u> , <i>Proc. Natl. Acad. Sci. USA</i> , <b>86</b> (4): 1173-7 (1989)	
	CL	LITTLE et al., <i>Clinical Chemistry</i> , <b>45</b> (8): 777-784 (1999)	
SP	CM	LIZARDI et al., <i>Bio Technology</i> , <b>6</b> : 1197-1202 (1988)	

Examiner Signature	/Suchira Pande/	Date Considered	02/04/2007
--------------------	-----------------	-----------------	------------

Substitute for form 1449/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				Application Number	10/825,908-Conf. # 8944
				Filing Date	April 16, 2004
				First Named Inventor	James M. Harris
				Art Unit	1637
				Examiner Name	Suchira Pande
Sheet	3	of	3	Attorney Docket Number	020187.0100/P-5677

SP	CN	LIZARDI et al., <u>Mutation Detection and Single-Molecule Counting Using Isothermal Rolling-Circle Amplification</u> , <i>Nat. Genet.</i> <b>19</b> (3): 225-32 (1998)	
	CO	SAIKI et al., <i>Science</i> , <b>230</b> : 1350-1354 (1985)	
	CP	SCHOONE et al., <u>Comparison of Dot Blot with in-situ Hybridization for the Detection of <i>Neisseria gonorrhoeae</i> in the Urethral Exudate</u> , <i>J. of Applied Bacteriology</i> , <b>66</b> :401-405 (1989)	
	CQ	STARY et al., <u>Comparison of Ligase Chain Reaction and Culture of Detection of <i>Neisseria gonorrhoeae</i> in Genital and Extragenital Specimens</u> , <i>J. of Clinical Microbiology</i> , <b>35</b> (1):239-242 (Jan. 1997)	
	CR	TOTTEN et al., <u>DNA Hybridization Technique for the Detection of <i>Neisseria gonorrhoeae</i> in Men with Urethritis</u> , <i>The Journal of Infectious Diseases</i> , <b>148</b> (3):462-471 (Sep. 1983)	
	CS	WALKER et al., <u>Isothermal in-vitro Amplification of DNA by a Restriction Enzyme/DNA Polymerase System</u> , <i>PNAS</i> , <b>89</b> :392-396 (1992)	
	CT	WALKER et al., <u>Strand Displacement Amplification-an Isothermal, in-vitro DNA Amplification Technique</u> , <i>Nucl. Acids Res.</i> , <b>20</b> :1691-1696 (1992)	
	CU	WATSON et al., <u>Recombinant DNA</u> , <i>Scientific American Books</i> , New York, pages 67-69, 1992	
SP	CV	WU et al., <i>Genomics</i> , <b>4</b> : 560-569 (1989)	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Suchira Pande/	Date Considered	02/04/2007
-----------------------	-----------------	--------------------	------------